JAN 2 8 2002

K013852

510(k) Summary
of Safety and Effectiveness

This submission covers the JOBST Ready-To-Wear Gauntlet, which falls under the device classification of medical support stockings (21 CFR §880.5780). It is equivalent to the JUZO Gauntlet, which is used for the same indications.

While the JUZO Gauntlet is flat knit and sewn together from fabric made of spandex, viscose and nylon yarns, the JOBST Ready-To-Wear Gauntlet is circular knit with spandex and nylon yarns. The thumb piece is then sewn in place in a second operation.

Both products are available in two compression ranges, 20-30 mmHg and 30-40 mmHg, the compression ranges most often prescribed by physicians for the indications involved. Both products are sized based on the palm and wrist measurements.

Compression is provided for all of these products by large elastic yarns that act circumferentially on the limb. The gradient compression present in these products helps reduce capillary leakage and improve capillary and lymphatic absorption. Consequently, they can be used to manage the same indications, i.e. edema and lymphedema. These products can also be used to manage hypertrophic scars.

The product being submitted is substantially equivalent to the predicate product in the materials used, mode of action, and indications for use and can be considered as safe and effective as the predicate product.

Date: November 16, 2001

Prepared by: Angelo R. Pereira
BSN-JOBST, Inc.
5825 Carnegie Boulevard
Charlotte, NC 28209
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BIOCOMPATIBILITY

Jobst Ready-To-Wear Gauntlet

The Jobst Ready-To-Wear (RTW) Gauntlet is made of spandex and nylon. These are the same fibers as used in the Jobst Custom garments (K925154) as well as in UltraSheer (Ultimate Stockings – K920444) and the Ready-To-Wear Arm Sleeve (K991570).

The RTW Gauntlets are dyed in the same dye loads as the UltraSheer stockings and so are exposed to the same dyes and dye chemicals.

Samples of UltraSheer stockings have previously been tested using the Fastox Primary Skin Irritation test. There was no evidence of any skin irritation.

The Fastox test is performed by NAMSA in Northwood, OH using three rabbits per test. The test area is observed at 24, 48 and 72-hour intervals.

Conclusion: Based on the above data it appears unlikely that use of the Jobst RTW Gauntlet will result in any significant skin irritation to the patient.

Angelo Pereira
Manager, Regulatory Affairs
BSN-JOBST, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2002

Ms. Angelo R. Pereira
Manager of Regulatory Affairs
BSN-Jobst, Incorporated
5825 Carnegie Boulevard
Charlotte, North Carolina 28209-4633

Re: K013852
Trade/Device Name: Jobst Ready-To-Wear Gauntlet
Regulation Number: 880.5780
Regulation Name: Compression Garments--Gauntlet
Regulatory Class: II
Product Code: DWL
Dated: November 16, 2001
Received: November 20, 2001

Dear Mr.Pereira:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number

Device name: **Jobst Ready-To-Wear Gauntlet**

Indications For Use: Over-the-Counter

Jobst Ready-To-Wear Gauntlet may be used under the direction of a Healthcare professional to manage the flowing conditions:

Edema
Lymphedema
Hypertrophic scars

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013852

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR Over The Counter Use** ✓
(Per 21 CFR 801.109)